

ZZZQUIL NIGHTTIME SLEEP-AID- diphenhydramine hydrochloride liquid

Procter & Gamble Manufacturing Company

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

ZzzQuil™

NIGHTTIME SLEEP-AID

Drug Facts

Active ingredients

(in each 30 mL dose cup or 2 tablespoons)

Diphenhydramine HCl 50 mg

Purpose

Nighttime sleep-aid

Uses

- for the relief of occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

Warnings

Do not use

- for children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin
- with other drugs that cause drowsiness such as antihistamines and nighttime cold/flu products
- Do not use with NyQuil

Ask a doctor before use if you have

- a breathing problem such as asthma, emphysema, or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- heart disease

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers or any other sleep aid

When using this product

- avoid alcoholic beverages and other drugs that cause drowsiness
- drowsiness will occur
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning

Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- take only one dose per day (24 hours) - see Overdose warning
- use dose cup or tablespoon

adults & children 12 yrs & over	One Dose = 30 mL (2 tablespoons) at bed time if needed or as directed by a doctor
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Other information

- **each 30 mL dose (2 tablespoons) contains:** sodium 23 mg
- store at room temperature
- protect from light. Does not meet USP <671>.

Inactive ingredients

citric acid, ethanol, FD&C blue #1, FD&C red #40, flavor, high fructose corn syrup, polyoxyl 40 stearate, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate dihydrate

Questions?

1-877-881-5813

**Dist. by Procter & Gamble,
Cincinnati OH 45202.**

PRINCIPAL DISPLAY PANEL - 354 ml Bottle Label

NEW *From the makers of* VICKS[®] NyQuil[®]

ZzzQuil[™]

NIGHTTIME SLEEP-AID

Diphenhydramine HCl

- **Non-Habit Forming**
- **Warming Berry Flavor**

Not for treating Cold or Flu

See Warnings

Alcohol 10%

12 FL OZ (354 ml)

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ZzzQuil™

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Failure to follow these warnings could result in serious consequences.

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When using this product

TAMPER EVIDENT: Do not use if printed shrinkband is missing or broken.



Drug Facts (continued)

- be careful when driving a motor vehicle or operating machinery

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AREA GAUGE
23900 01398



ZZZQUIL NIGHTTIME SLEEP-AID

diphenhydramine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37000-500
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety		
Ingredient Name		Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)		DIPHENHYDRAMINE HYDROCHLORIDE 50 mg in 30 mL

Inactive Ingredients	
Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ALCOHOL (UNII: 3K9958V90M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

Product Characteristics			
Color	PURPLE	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37000-500-06	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:37000-500-12	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

3	NDC:37000-500-24	2 in 1 PACKAGE, COMBINATION		
3	NDC:37000-500-12	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:37000-500-36	3 in 1 PACKAGE, COMBINATION		
4	NDC:37000-500-12	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part338	12/08/2011	

Labeler - Procter & Gamble Manufacruing Company (004238200)

Revised: 9/2014

Procter & Gamble Manufacruing Company